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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,567	08/05/2003	A. Wesley Prais	102-523 DIV/CON/CIP II	6974
32752 7590 08/08/2007 DAVID W. HIGHET VP & CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY (Hoffman & Baron) 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			EXAMINER KOHARSKI, CHRISTOPHER	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 08/08/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/634,567

Applicant(s)

PRAIS ET AL.

Examiner

Christopher D. Koharski

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3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 31-59 is/are pending in the application.
- 4a) Of the above claim(s) 11-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 19-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges the reply filed 7/18/2007 in which claims 28, 32-34, 38, and 50 were amended. Currently claims 1-28 and 31-50 are pending for examination in which claims 11-18 are withdrawn from a previous election restriction.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-28 and 31-59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-64 of copending Application No. 10/635066. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claims are drawn to the same inventive aspect of the multi-beveled needle.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 19-25, 28, and 31-47 are rejected under 35 U.S.C 103(a) as being unpatentable over Baldwin et al. (3,071,135) or Berke et al. (4,561,445).

Regarding claims 1-8, 19-25, 28, and 31-47, Baldwin et al. discloses a needle cannula comprising a needle (10) with a plurality of planar bevels with different angles relative to the central axis, with a primary bevel (17), a pair of tip bevels (13), and a pair of middle bevels (12) located intermediate to said tip bevel and primary bevel (Figures 1-3).

Regarding claims 1-10, 19-25, 28, and 31-47, Berke et al. discloses a needle cannula with plurality of planar bevels (12, 11, 22, 24, 34, 36) extending at different

angles relative to said central axis, including primary bevel, pair of tip bevels, and a pair of middle bevels intermediate said primary bevel and said tip bevels (Figures 6-11).

Baldwin et al. or Berke et al. meets the claim limitations as described above except for the specific needle diameters, materials, syringe barrel, bevel lengths and rotational angles.

At the time of the invention it would have been obvious for one of ordinary skill in the art to modify either Baldwin or Berke et al. for use with a syringe and to have the specific angles and bevel lengths being chosen for either the planar angle, the rotational angle and bevel length because of routine experimentation, and further more, it would have taken only routine skill in the art to modify the teaches of Baldwin or Berke et al. to the angle, size and dimensions of the needle diameters of the claimed invention. Furthermore, there is no specific criticality or unexpected result being derived from the angles chosen, thus making this modification a matter of design choice, and well within the skill of the ordinary artisan, to determine the optimum results through routine experimentation.

### ***Claim Rejections - 35 USC § 103***

Claim 50 is rejected under 35 U.S.C 103(a) as being unpatentable over Hickley (2,697,438). Hickley discloses non-coring hypodermic needle.

Regarding claim 50, Hickley discloses a needle cannula (Figure 1) with a plurality of discrete bevels (Figure 3) (10, 8) wherein one of said plurality of discrete bevels is located furthest from said point and has a shorter length than any other (8) (Figures 1-4).

Hickley meets the claim limitations as described above except for the specific needle diameters and syringe barrel.

At the time of the invention it would have been obvious for one of ordinary skill in the art to modify Hickley for use with a syringe and to have the diameter ranges chosen because of routine experimentation, and further more, it is well known in the art to vary needle sizes according to use during treatment. Furthermore, there is no specific criticality or unexpected result being derived from the diameters chosen, thus making this modification a matter of design choice, and well within the skill of the ordinary artisan, to determine the optimum results through routine experimentation.

***Claim Rejections - 35 USC § 103***

Claims 51-57 are rejected under 35 U.S.C 103(a) as being unpatentable over Hickley in view of Baldwin et al. (3,071,135) or Berke et al. (4,561,445).

Hickley meets the claim limitations as described above except for the additional needle bevels and rotational angles. However, Baldwin or Berke et al. teaches different beveled needle cannulas.

Regarding claims 51-57, Baldwin et al. teaches a needle cannula comprising a needle (10) with a plurality of planar bevels with different angles relative to the central axis, with a primary bevel (17), a pair of tip bevels (13), and a pair of middle bevels (12) located intermediate to said tip bevel and primary bevel (Figures 1-3). Berke et al. teaches a needle cannula with plurality of planar bevels (12, 11, 22, 24, 34, 36) extending at different angles relative to said central axis, including primary bevel, pair of

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tip bevels, and a pair of middle bevels intermediate said primary bevel and said tip bevels (Figures 6-11).

At the time of the invention, it would have been obvious to add the additional bevels of Baldwin or Berke et al. in order to further sharpen the needle tip to ease insertion. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosures of Baldwin or Berke et al.

Additionally, the time of the invention it would have been obvious for one of ordinary skill in the art to modify the modified Hickley to have the specific angle being chosen for either the planar angle or the rotational angle because of routine experimentation, and further more, it would have taken only routine skill in the art to modify the device Hickley to the angle, size and dimension of the claimed invention. Furthermore, there is no specific criticality or unexpected result being derived from the angles chosen, thus making this modification a matter of design choice, and well within the skill of the ordinary artisan, to determine the optimum results through routine experimentation.

### ***Claim Rejections - 35 USC § 103***

Claims 9-10, 26-27, 36-37, 48-49 and 58-59 are rejected under 35 U.S.C 103(a) as being unpatentable over Baldwin et al. (or Berke et al. or Hickley) in view of Hausser (5,385,555). Baldwin et al. (or Berke et al. or Hickley) meets the claim limitations as

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described above except for a needle shield with the specific Shore hardness's as claimed.

However, Hausser teaches a lockable safety shield for a hypodermic syringe.

Regarding claims 9-10, 26-27, 36-37, 48-49 and 58-59, Hausser teaches a needle shield (36) composed of a thermoplastic material (Figures 1-3).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the needle shield of Hausser with the needle shield material properties as claimed by Applicant, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

At the time of the invention, it would have been obvious to use the needle shield of Hausser with the needle of Baldwin et al. (or Berke et al. or Hickley) because the needle shield aids in user safety and protection against needle sticks. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Hausser.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-28 and 31-59 have been considered but are moot in view of the new ground(s) of rejection.



**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Saito (5,820,609).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

7/26/07

  
NICHOLAS D. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3763

  
Christopher D. Koharski  
AU 3763